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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/784,401	02/23/2004	Peter M. Bonutti	780-A04-002-1	1827

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PAUL D. BIANCO: FLEIT, KAIN, GIBBONS,
GUTMAN, BONGINI, & BIANCO P.L.
21355 EAST DIXIE HIGHWAY
SUITE 115
MIAMI, FL 33180

EXAMINER

GETTMAN, CHRISTINA DANIELLE

ART UNIT	PAPER NUMBER
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3734

MAIL DATE	DELIVERY MODE
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07/05/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

mf

Office Action Summary	Application No. 10/784,401	Applicant(s) BONUTTI, PETER M.	
	Examiner M. Thomas Andersen	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2007.
 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
 4a) Of the above claim(s) 12-18 is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 1-11 and 19-31 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3/01/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgement is made of the response filed 3/01/2007, to the non-final Office action dated 12/01/2006.

Response to Arguments

Applicant's arguments filed 3/01/2007 have been fully considered but they are not persuasive.

1. Applicant has not shown how the amendments are supported by the specification. It is unclear how something, e.g. a needle, can be moved through tissue without the aid of mechanical force. It is presumed that Applicant meant mechanical force supplied by the physician. However, this is not claimed. The needle itself exudes mechanical force on the tissue as it penetrates. For this reason the amended claims are rejected under 35 U.S.C. 112, first paragraph.

2. Applicant has not submitted arguments regarding the capability of either the Holmes or the Caspari references. Should Applicant amend the claims to add the limitation that the mechanical force is supplied by a physician, the art of record is still considered *capable* of providing a magnetic field of sufficient strength to move a medical implement through tissue. The magnet in Holmes is considered capable of attracting a magnetic component through tissue because the thickness of the tissue is not claimed. As the type of tissue is not enumerated in the claims, an argument against the capability interpretation of the prior art may be futile.

The previous rejection as well as a response to Applicant's arguments follow:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 8 and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Again, it is unclear how something, e.g. a needle, can be moved through tissue without the aid of mechanical force.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 4, 6-10, 19-20, 22, 24-29, and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Holmes, U.S. 5,417,701.

Holmes discloses a suturing instrument using magnets. Specifically, Holmes discloses, "With the needle in the desired position and orientation, the surgeon manipulates the instrument to insert the needle into, and part way through the tissue to be sutured. She then uses a second, similar instrument to grasp the needle and pull it the rest of the way through the tissue. This second instrument may include a magnet,

which is preferably of lesser strength than the magnet in the first instrument. When this second instrument pulls the needle out of the tissue, the included magnet draws the needle into proper position within its jaws and holds the needle in this position until the needle is transferred to the first instrument.”

Holmes discloses a permanent magnet on the ‘first instrument’ generating a magnetic field of sufficient strength to move the implement through the tissue. Moving the two magnetic elements, one on the first instrument and one on the second instrument, the magnetic field is varied to move the medical implement through the tissue. The magnet is positioned external to the tissue. The magnet is selectably positionable to move the medical implement through the tissue. The second instrument can be said to contain a magnetizable material; or, in the alternative, the needle can be said to comprise a magnetizable material.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3, 5, 11, 21, 23, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holmes, as applied to claims 1, 8, and 26 above, in view of Burns, U.S. 5,851,185.

Holmes does not disclose using an electromagnet. However, Burns discloses that it is well known in the art to use an electromagnet in the place of a permanent

magnet. See, Burns col. 2, lines 53-56. It would have been obvious to one of ordinary skill in the art to use an electromagnet so as to better control the magnetic field when drawing the needle through tissue.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to M. Thomas Andersen whose telephone number is (571) 272-8024. The examiner can normally be reached on M-F 8AM-4:30PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3734

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

M. Thomas Andersen

A handwritten signature in black ink, appearing to read "MJ Hayes", with a stylized, cursive script.

MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER